LUMEN BIOMEDICAL

AUG 17 2011

Lumen Biomedical, Inc.
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510(k) Summary

Contact Person:	Michelle Straight Director of Quality Assurance and Regulatory Affairs
Summary Date:	July 12, 2011
Product Trade Name:	FiberNet® Embolic Protection System
Common Name:	Embolic Protection Device
Classification Name:	Catheter, Percutaneous
Predicate(s):	FiberNet Embolic Protection System (K082348)
Intended Use:	The FiberNet® Embolic Protection System is indicated for use as a guidewire and emboli protection system to capture and remove embolic material (thrombus/debris) produced while performing percutaneous transluminal interventional procedures in carotid arteries in high surgical risk patients with reference vessel diameters of 3.5 to 7.0 mm.
Device Description:	The FiberNet Embolic Protection System consists of a fiber filter on a 0.014" guide wire with attachable actuator tool and a 0.014" guidewire compatible aspiration catheter with attachable stopcock assembly. System accessories included in the package consist of two 30 ml syringes, a peel-away introducer and a 40μm cell strainer cup.
Indication for Use:	The FiberNet Embolic Protection System is indicated for use as a guidewire and emboli protection system to capture and remove embolic material (thrombus/debris) produced while performing percutaneous transluminal interventional procedures in carotid arteries in high surgical risk patients with reference vessel diameters of 3.5 to 7.0 mm.
Technological Characteristics	The FiberNet Embolic Protection System has the same technological characteristics as the predicate device except for the following: • Addition of antioxidants to the catheter material • Addition of a white colorant near the RX port • Change in the distal liner material to a material used in the mid shaft of the catheter • Increase in the proximal shaft OD

K111987

Safety & Performance:

The results of the *in vitro* bench and biocompatibility testing demonstrated the system is equivalent to the predicate device.

Bench tests performed included:

- Wall integrity/aspiration rate
- Push/track
- Stent crossing
- Torque response
- Tip stiffness
- Torque strength
- Liquid leakage under aspiration
- Liquid leakage pressure – hub/catheter
- Kink resistance
- Tensile – bonds and joints (catheter port and hub)
- Device retraction

Biocompatibility was supported by material manufacturer data and the following additional tests:

- Cytotoxicity
- Hemolysis (direct and extract)
- Complement Activation
- Unactivated Partial Thromboplastin Time Assay (direct and indirect)
- In vivo Thrombogenicity
- Physical Chemical

Conclusion:

This product is substantially equivalent[1] and acceptable for the intended use.

[1] This document uses the term "substantial equivalent" as intended in 21 CFR 807.87 and not as defined in Title 36 of the U.S. Code.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Michelle Straight
Director of Quality Assurance and Regulatory Affairs
Lumen Biomedical, Inc.
10900 73rd Ave. N, Suite 150
Maple Grove, MN 55369

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Re: K111987
Trade/Device Name: Fibernet Embolic Protection System
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: NTE
Dated: July 12, 2011
Received: July 13, 2011

Dear Ms. Straight:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K111987

Device Name: FiberNet® Embolic Protection System

Indications for Use:

The FiberNet® Embolic Protection System is indicated for use as a guidewire and emboli protection system to capture and remove embolic material (thrombus/debris) produced while performing percutaneous transluminal interventional procedures in carotid arteries in high surgical risk patients with reference vessel diameters of 3.5 to 7.0 mm.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K111987